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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/762,492	01/23/2004	Fredric R. Bloom	0942.5490002	4921
26111 7590 09/12/2007 STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C. 1100 NEW YORK AVENUE, N.W. WASHINGTON, DC 20005			EXAMINER HINES, JANA A	
			ART UNIT 1645	PAPER NUMBER
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/762,492

Applicant(s)

BLOOM ET AL.

Examiner

Ja-Na Hines

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 31 May 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 2-14 and 77-79 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2-14 and 77-79 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Amendment Entry***

1. The amendment of May 31, 2007 has been entered. The examiner acknowledges the amendment to the declaration. Claims 1, 15-76 and 80-107 are cancelled. Claims 2-14 and 77-79 have been amended. Claims 2-14 and 77-79 are under consideration in this office action.

***Withdrawal of Rejections***

2. The following rejections have been withdrawn in view of applicants' amendments and arguments:

- a) The deposit rejection of claims 1-14 and 77-79 are rejected under 35 U.S.C. 112, first paragraph; and
- b) The rejection of claims 1-14 under 35 U.S.C. 101.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 2-14, and 77-79 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a) Claims 2-14, 77 and 79 are rejected because it cannot be determined whether the "said isolated *E. coli*" in line 2 of claim 2 is referring to the isolated *E. coli* of line 1 or *E. coli* MM294. Therefore, clarification is required to overcome the rejection.

b) Claim 78 recites the phrase "derivatives thereof" however it is unclear how to define "derivatives". The specification does not teach how to make derivatives from JDP674. The derivative language is vague and indefinite because the characteristics needed to determine whether an unknown could be considered a derivative of JDP674 are unknown. The specification neither discloses a definition for a derivative, nor does it teach a requisite amount of retained qualities needed or characteristics necessary to determine derivatives of JDP674. Therefore the claims are unclear and clarification is required to overcome the rejection.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 2-14, 77 and 79 are rejected under 35 U.S.C. 102(b) as being anticipated by Bloom et al., (WO 00/78925 dated December 28, 2000).

Claim 2 is drawn to an isolated *Escherichia coli* having a growth rate that is at least 5% greater than the growth rate of *E. coli* MM294, wherein said isolated *E. coli* are

resistant to infection by bacteriophage Wphi. Claim 3 is drawn to an isolated *Escherichia coli* having a growth rate that is at least 5% greater than the growth rate of *E. coli* MM294, wherein said isolated *E. coli* are resistant to infection by bacteriophage Mu. Claim 4 is drawn to the *E. coli* not containing any detectable genetic material of one or more bacteriophage types selected from the group consisting of Mu, T1, T2, T3, T4, T5, T6 and T7. Claims 5-7 are drawn to the *E. coli* lacking detectable levels of at least one endogenous plasmid. Claim 8 is drawn to the *E. coli* containing one or more genotype markers selected from the group consisting of: *recA*-, *lacZ*-,  $\Delta lon$ , *ompT*-, *endA1*, *maE*-, *mal*-, *hsdR17*(*rK*-, *inK*+), *hsdS20*(*rB*-, *mB*+), *merA*, *mcrB*, *mrr*, *deoR*, *supE* and *supF*. Claim 9 is drawn to the *E. coli* contain one or more genotype markers selected from the group consisting of: *recA1*, *recA13*,  $\Delta recA$ , *lacX74*, and *lacZ* $\Delta M15$ . Claim 10 is drawn to the *E. coli* containing an F' episome. Claim 11 is drawn to the *E. coli* having a growth rate that is at least 25% greater than the growth rate of *E. coli* MM294.

Claim 12 is drawn to the *E. coli* having a growth rate that is at least 50% greater than the growth rate of *E. coli* MM294. Claim 13 is drawn to the *E. coli* having a growth rate that is at least 100% greater than the growth rate of *E. coli* MM294. Claim 14 is drawn to the *E. coli* being *E. coli* strain W. Claim 77 is drawn to a composition comprising *E. coli*, wherein the *E. coli* of said composition have a growth rate that is at least 5% greater than the growth rate of *E. coli* MM294, and wherein said *E. coli* is resistant to infection by bacteriophage Mu. Claim 78 is drawn to the composition containing *E. coli* that is JDP674 or derivatives thereof. Claim 79 is drawn to a

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composition comprising *E. coli*, wherein the *E. coli* of said composition have a growth rate that is at least 5% greater than the growth rate of *E. coli* MM294, and wherein said *E. coli* do not contain detectable levels of genetic material of bacteriophage Wphi.

Bloom et al., teach rapidly growing *E. coli* strain W that lacks endogenous plasmids, and teaches strains BRL3781, BRL3784 and *recA*<sup>-</sup> derivatives (page 3, lines 23-28). It is noted that the instant specification at page 4, para. [0010], states that *E. coli* strain W does not contain the genetic material of bacteriophage Wphi and/or does not contain the genetic material of bacteriophage Mu and/or is resistant to infection, thereby teaching strain W inherently does not contain any detectable levels of bacteriophage genetic material from the Wphi or Mu bacteriophage and is resistant to infection by the bacteriophages.

Bloom et al., teach strains wherein the modification includes alterations of the *recA*<sup>-</sup> genotype such as *recA1/recA13* or *recA* deletions, a *lacZ*<sup>-</sup> genotype that allows for alpha complementation such as *lacX74 lacZΔM15* or other *lacZ* deletions a protease deficient genotype such as *Δlon* and/or *ompT*<sup>-</sup>, an endonuclease minus genotype such as *endA1*, a genotype suitable for M13 phage infection by including the F' episome, a restriction negative, modification positive genotype such as *hsdR17*(*r<sub>K</sub>*<sup>-</sup>, *m<sub>K</sub>*<sup>+</sup>), a restriction negative, modification negative genotype such as *hsdS20*(*r<sub>B</sub>*<sup>-</sup>, *m<sub>B</sub>*<sup>-</sup>), a methylase deficient genotype such as *mcrA* and/or *mcrB* and/or *mrr*, a genotype suitable for taking up large plasmids such as *deoR*, a genotype containing suppressor mutations such as *supE* and/or *supF*. Bloom et al., teach other suitable modifications are known to those skilled in the art and such modifications are

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considered to be within the scope of the present invention (pages 4-5, lines 22-6).

Bloom et al., teach the rapid growing bacteria that have an increased growth rate that is greater than 5%, 10%, 25%, 50%, 75%, 100%, 150%, 200% than the growth rate of the reference microorganism which is *E.coli* MM294 (as known as ATCC 33625) (page 10, lines 14-19). Bloom et al., teach compositions comprising the rapidly growing microorganisms (page 17, lines 30-32). Example 3 teaches the construction of BRL3582 a *recA*<sup>-</sup> *E.coli* W contained in broth. Example 4 teaches *E.coli* W derivatives lacking native plasmids contained in medium.

Thus Bloom et al., teach the inventions of claims 2-14 and 77-79.

### ***Response to Arguments***

5. Applicant's arguments filed May 31, 2007 have been fully considered but they are not persuasive.

Applicants urge that Bloom et al., do not teach isolated *E. coli* or compositions comprising *E. coli* that are specifically resistant to infection by bacteriophage Wphi or Mu; therefore, Bloom does not anticipate the present claims.

However, contrary to applicants' assertions, the disclosed W strain of *E. coli* is known to be resistant to infection by bacteriophages Wphi or Mu. There is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of invention, but only that the subject matter is in fact inherent in the prior art reference. *Schering Corp. v. Geneva Pharm. Inc.*, 339 F.3d 1373, 1377, 67

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USPQ2d 1664, 1668 (Fed. Cir. 2003) (rejecting the contention that inherent anticipation requires recognition by a person of ordinary skill in the art before the critical date and allowing expert testimony with respect to post-critical date clinical trials to show inherency); see also *Toro Co. v. Deere & Co.*, 355 F.3d 1313, 1320, 69 USPQ2d 1584, 1590 (Fed. Cir. 2004)("[T]he fact that a characteristic is a necessary feature or result of a prior-art embodiment (that is itself sufficiently described and enabled) is enough for inherent anticipation, even if that fact was unknown at the time of the prior invention.").

Therefore applicants statements that Bloom et al., do not specifically recite resistance to the bacteriophages Wphi or Mu is not persuasive because the W strain *E. coli* of Bloom et al., appears to be identical to the instantly claimed isolated *E. coli* except that the Bloom et al., reference is silent as to the inherent characteristic of the stain being resistant to infection by bacteriophage Wphi or Mu. Thus, applicants' arguments are not persuasive and the rejection is maintained.

### ***Conclusion***

6. No claims allowed.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within



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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Jeffery Siew, can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ja-Na Hines  
August 23, 2007



  
MARK NAVARRO  
PRIMARY EXAMINER